

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 20

## UNITED STATES PATENT AND TRADEMARK OFFICE

### BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOSEPH A. HASLWANTER and WILLIAM F. RENCHER

Appeal No. 2004-1188  
Application No. 09/940,784

ON BRIEF



Before SCHEINER, ADAMS, and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

#### DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 15-33, which are all the claims pending in the application.

Claims 15 and 29 are illustrative of the subject matter on appeal and are reproduced below:

15. An aqueous nasal spray composition prepared by combining ingredients comprising oxymetazoline hydrochloride and two or more linear polymers of 1-Vinyl-2-pyrrolidone having different average molecular weights.
29. An aqueous nasal spray composition prepared by combining ingredients comprising: 0.01 to 0.1 percent by weight/volume of oxymetazoline hydrochloride; a linear polymer of 1-Vinyl-2-pyrrolidone having an average molecular weight about 40,000; a linear polymer of 1-Vinyl-2-pyrrolidone having an average molecular

weight about 360,000; and a water-soluble polyethylene glycol; the total concentration of the linear polymer ingredients being about 0.5 to about 15 percent by weight/volume.

The references relied upon by the examiner are:

Shimizu et al. (Shimizu)	4,728,509	Mar. 1, 1988
Parnell	5,015,474	May 14, 1991
Gilbert et al. (Gilbert)	5,116,847	May 26, 1992

Rybacki et al. (Rybacki), "Auxiliary Substances in Technology of Drug Form," Library of a Pharmacist, Vol. 7, pp. 1-12 (1980)

#### GROUNDS OF REJECTION

Claims 15-17 and 21-28 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Shimizu, Gilbert and Parnell.

Claims 18-20 and 29-33 stand rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Shimizu, Gilbert and Parnell, further in view of Rybacki.

We reverse.

#### DISCUSSION

##### The combination of Shimizu, Gilbert and Parnell:

According to the examiner (Answer, page 3), Shimizu disclose an aqueous nasal spray composition comprising, inter alia, a drug and polyvinylpyrrolidone (PVP) having an average molecular weight of about 25,000-120,000 daltons. The examiner recognizes, however, that Shimizu does not teach the (1) use of two or more PVPs having different average molecular weights, or (2) oxymetazoline hydrochloride. Answer, page 4. The examiner relies on Gilbert and Parnell to make up these deficiencies.

The examiner finds (*id.*), "Gilbert teaches [a] nasal spray composition comprising active agent, such as ... oxymetazoline hydrochloride...." In addition, the examiner finds (*id.*), Parnell teaches a nasal spray composition comprising, inter alia, PVP as a thickener. According to the examiner (Answer, page 6), "Parnell is relied upon solely for the teachings that more than one polymer can be used as additive agents in a nasal spray composition." To be clear, however, we note that the examiner does not identify, and we do not find, a teaching in Parnell that suggests using two or more PVPs having different average molecular weights in the same composition. Nevertheless, the examiner concludes (Answer, page 4),

it would have been *prima facie* [sic] obvious for one of ordinary skill in the art to modify Shimizu's formulation with the active drug, and the aqueous carriers in view of the teachings of Gilbert, and PVP as thickening agent in view of the teachings of Parnell to obtain the claimed invention, because the references teach the advantageous results in the use of aqueous nasal formulation useful for the treatment of respiratory diseases, such as allergy, itchy nose, and runny nose. The expected result would be an aqueous nasal spray formulation comprising oxymetazoline HCL and PVP that is stable, alleviate dryness, and reduce nose-irritation.

Conspicuous by its absence, is the failure of the examiner to identify a teaching, in the cited prior art, of the use of two or more linear polymers of 1-Vinyl-2-pyrrolidone having different average molecular weights. Upon review of the cited prior art, we find that while the cited references teach that PVP is available in a variety of different average molecular weights, none of the references relied upon teach or suggest the use of two or more PVPs having different average molecular weights in the same composition. As appellants

point out (Reply Brief, page 2), “[a]bsent the mention in any reference of record that the combination of two or more polyvinylpyrrolidone polymers having different average molecular weights, as required by the rejected claims, would be useful in a nasal spray composition, there simply can be no prima facie case for obviousness....” We agree.

In this regard, we note the examiner’s statement (Answer, page 5), “although Shimizu does not teach [a] mixture of PVP having different average molecular weights, the examples of Shimizu suggest using polyvinylpyrrolidone having different average molecular weights for [a] similar purpose desired by the appellant....” While Shimizu teach the use of PVP having different average molecular weights, Shimizu do not teach or suggest the use of PVPs having different average molecular weights in the same composition. Neither Gilbert nor Parnell make up for the deficiency in Shimizu. Accordingly, we disagree with the examiner’s conclusion (*id.*), “it would have been obvious for one of ordinary skill in the art to, by routine experimentation[,] combine the PVP polymers in the examples to obtain the claimed invention.”

As set forth in In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000), citations omitted:

A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. ... Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one “to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher.”

...  
Most if not all inventions arise from a combination of old elements.  
... Thus, every element of a claimed invention may often be found  
in the prior art. ... However, identification in the prior art of each  
individual part claimed is insufficient to defeat patentability of the  
whole claimed invention. ... Rather, to establish obviousness  
based on a combination of the elements disclosed in the prior art,  
there must be some motivation, suggestion or teaching of the  
desirability of making the specific combination that was made by  
the applicant.

In other words, "there still must be evidence that 'a skilled artisan, ... with  
no knowledge of the claimed invention, would select the elements from the cited  
prior art references for combination in the manner claimed.'" Ecolochem Inc. v.  
Southern California Edison, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1075-76  
(Fed. Cir. 2000). At best, the statement of the rejection establishes that  
individual parts of the claimed invention were known in the prior art. In this  
regard, we agree with appellants (Reply Brief, page 2), "[t]he rejection appears to  
be based simply on a finding that all of the appellants' required ingredients are  
known in the art. However, there is no suggestion in the applied documents to  
make any combination of ingredients that will fully meet the limitations of the  
rejected claims."

For the foregoing reasons, we reverse the rejection of claims 15-17 and  
21-28 under 35 U.S.C. § 103 as being unpatentable over the combination of  
Shimizu, Gilbert and Parnell.

The combination of Shimizu, Gilbert and Parnell, further in view of Rybacki:

The examiner relies on Shimizu, Gilbert and Parnell as set forth above.  
According to the examiner (Answer, page 4), "[t]he references are silent as to the

specific molecular weight of PVP being claimed." To make up for this deficiency, the examiner relies on Rybacki. According to the examiner (Answer, page 5), "Rybacki teaches PVP having [a] molecular weight of about 10,000, 40,000, 160,000 and 360,000 are useful in [the] pharmaceutical art as a binder, solubilizer, and thickener (pages 8-10)." Based on this evidence, the examiner concludes (*id.*), "it would have been obvious for one of ordinary skill in this art to modify Gilbert's formulation using PVP having the molecular weight of Rybacki with the expectation of [obtaining] at least [a] similar result, because the references teach that PVP is useful in liquid nasal formulation[s]."

We note, however, that the examiner does not identify, and we do not find, a teaching in Rybacki that suggests using two or more PVPs having different average molecular weights in the same composition. Therefore, Rybacki fails to make up for the deficiency in the combination of Shimizu, Gilbert and Parnell as discussed above. Accordingly, we reverse the rejection of claims 18-20 and 29-33 under 35 U.S.C. § 103 as being unpatentable over the combination of Shimizu, Gilbert and Parnell, further in view of Rybacki.

REVERSED

*Toni R. Scheiner* )  
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Administrative Patent Judge )  
*Donald E. Adams* ) BOARD OF PATENT  
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